

08/ 863794

FILE 'USPAT' ENTERED AT 15:52:11 ON 08 JUL 1999

* U. S. P A T E N T T E X T F I L E *
*
* THE WEEKLY PATENT TEXT AND IMAGE DATA IS CURRENT *
* THROUGH July 06, 1999 *
*
*

=>

=>

=> s prosthesis

L1 7861 PROSTHESIS

=> s 11/ti

L2 1939 (PROSTHESIS/TI)

=> s 11/clm

L3 3317 (PROSTHESIS/CLM)

=> s 12 and 13

L4 1690 L2 AND L3

=> s 14 and liner/clm and (knee or limb)/clm

14174 LINER/CLM

3410 KNEE/CLM

4026 LIMB/CLM

L5 6 L4 AND LINER/CLM AND (KNEE OR LIMB)/CLM

=> d 1-6

1. 5,888,216, Mar. 30, 1999, **Prosthesis** liner for below-knee amputees; Louis J. Haberman, 623/36 [IMAGE AVAILABLE]

2. 5,702,463, Dec. 30, 1997, Tibial **prosthesis** with polymeric liner and liner insertion/removal instrument; Albert Pothier, et al., 623/20; 606/99; 623/18 [IMAGE AVAILABLE]

3. 5,314,497, May 24, 1994, Apparatus and method for sealing a liner to a **prosthesis**; John N. Fay, et al., 623/34, 33, 37 [IMAGE AVAILABLE]

4. 5,258,037, Nov. 2, 1993, Prosthetic liner and method of making the liner with a **prosthesis** socket; Carl A. Caspers, 623/36, 33 [IMAGE AVAILABLE]

5. 5,171,282, Dec. 15, 1992, Femoral member for knee **prosthesis**; Michel Pequignot, 623/20, 18 [IMAGE AVAILABLE]

6. 4,094,017, Jun. 13, 1978, Knee joint **prosthesis** with patellar-femoral contact; Larry Stanford Matthews, et al., 623/20 [IMAGE AVAILABLE]

=> d his

(FILE 'USPAT' ENTERED AT 15:52:11 ON 08 JUL 1999)

L1 7861 S PROSTHESIS
L2 1939 S L1/TI
L3 3317 S L1/CLM
L4 1690 S L2 AND L3
L5 6 S L4 AND LINER/CLM AND (KNEE OR LIMB)/CLM

=> s gel and l4

168863 GEL
L6 136 GEL AND L4

=> s l4 and gel/clm or l4/ and gel/ti

QUALIFICATION NOT VALID FOR 'L4'

=> s l4 and (gel/clm or gel/ti)

19329 GEL/CLM
1888 GEL/TI
L7 53 L4 AND (GEL/CLM OR GEL/TI)

=> s l7 and styrene

102391 STYRENE
L8 2 L7 AND STYRENE

=> d 1-2

1. 4,264,990, May 5, 1981, Mammary **prosthesis**; Robert S. Hamas, 623/8 [IMAGE AVAILABLE]

2. 3,905,376, Sep. 16, 1975, Pedicure **prosthesis** for the metatarsal arch of the foot; Amos N. Johnson, et al., 36/154; 264/46.6, 222, 313, 443, 496, DIG.30; 602/7 [IMAGE AVAILABLE]

=> s l7 and block

627389 BLOCK
L9 2 L7 AND BLOCK

=> d 1-2

1. 5,407,445, Apr. 18, 1995, **Gel** composition for implant **prosthesis** and method of use; Daiva K. Tautvydas, et al., 623/8, 11, 66 [IMAGE AVAILABLE]

2. 3,665,520, May 30, 1972, SURGICALLY IMPLANTABLE BREAST **PROSTHESIS**; Colette Perras, et al., 623/8; 128/DIG.21; 450/38 [IMAGE AVAILABLE]

=> d 1 bib ti ab kwic

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July 06,1999 for U.S. Patent Image Data.

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7:30am - 5:00pm Saturday, Sunday, Holidays

APS is unavailable Thanksgiving Day, Christmas Day,
and New Year's Day.

1. 5,888,216, Mar. 30, 1999, **Prosthesis** liner for below-knee amputees; Louis J. Haberman, 623/36 [IMAGE AVAILABLE]
2. 5,258,037, Nov. 2, 1993, Prosthetic liner and method of making the liner with a **prosthesis** socket; Carl A. Caspers, 623/36, 33 [IMAGE AVAILABLE]

US PAT NO: 5,407,445 [IMAGE AVAILABLE] L9: 1 of 2
DATE ISSUED: Apr. 18, 1995
TITLE: Gel composition for implant **prosthesis** and method
of use
INVENTOR: Daiva K. Tautvydas, Atlanta, GA
Mannarsamy Balasubramanian, Roswell, GA
R. Martin Emanuele, Alpharetta, GA
ASSIGNEE: Cytrx Corporation, Norcross, GA (U.S. corp.)
APPL-NO: 08/064,519
DATE FILED: May 19, 1993
ART-UNIT: 338
PRIM-EXMR: David Isabella
LEGAL-REP: Jones & Askew

US PAT NO: 5,407,445 [IMAGE AVAILABLE] L9: 1 of 2
TITLE: Gel composition for implant **prosthesis** and method
of use

ABSTRACT:

In accordance with the present invention, a composition and method is provided for a biocompatible filler for prostheses. The composition and method relate to certain polyoxyethylene/polyoxypropylene **block** copolymers which have gelling properties at body temperature and are ideally suited for use as fillers for a soft tissue prosthesis such as a breast implant.

TITLE: Gel composition for implant **prosthesis** and method
of use

ABSTRACT:

In . . . a composition and method is provided for a biocompatible filler for prostheses. The composition and method relate to certain polyoxyethylene/polyoxypropylene **block** copolymers which have gelling properties at body temperature and are ideally suited for use as fillers for a soft tissue. . .

SUMMARY:

BSUM(2)

The . . . relates to a biocompatible gel composition for use in implantable prostheses. More particularly, the present invention relates to certain polyoxyethylene/polyoxypropylene **block** copolymers which have gelling properties that make them ideally suited for use as fillers for a soft tissue prosthesis such. . .

SUMMARY:

BSUM(19)

In . . . in an aqueous solution, which is stable to sterilization. The polymeric materials which encompass the present invention are polyoxyethylene/ polyoxypropylene **block** copolymers.

SUMMARY:

BSUM(20)

The preferred composition according to the present invention comprises a solution of polyoxyethylene-polyoxypropylene **block** copolymer with the

following general formula:

SUMMARY:

BSUM(23)

The preparation of aqueous gels of polyoxyethylene-polyoxypropylene **block** copolymers is described in U.S. Pat. Nos. 3,867,533; 3,748,276; and 3,740,421, all of which are incorporated herein by reference. None.

SUMMARY:

BSUM(24)

Because certain of these polyoxyethylene-polyoxypropylene **block** copolymers are liquids at low temperatures, and gels at body temperatures, the aqueous gel compositions are ideal for filling a prosthesis such as a breast implant. This family of polyoxyethylene-polyoxypropylene **block** copolymers is also substantially non-toxic, and exhibits improved lubrication and improved radiolucence. The copolymers are also biocompatible. If the implant.

DETDESC:

DETD(2)

The present invention contemplates a biocompatible gel comprising a solution of a polyoxyethylene/polyoxypropylene **block** copolymer. These biocompatible gels are particularly suited for filling the lumen of a soft tissue prosthesis that can be used.

DETDESC:

DETD(3)

The aqueous gel composition of the present invention comprises a solution of a polyoxyethylene-polyoxypropylene **block** copolymer that has the physical property of being a liquid at room temperature or below and a gel at body.

DETDESC:

DETD(4)

The polyoxyethylene-polyoxypropylene **block** copolymer has the following general formula:

DETDESC:

DETD(7)

The polyoxyethylene-polyoxypropylene **block** copolymer preferably has a hydrophobe represented by $(C_{3.3}H_{6.6}O)_{a.3}$ with a molecular weight between approximately 1750 and 6000 Daltons. . . molecular weight of the $(C_{3.3}H_{6.6}O)_{b.3}$ between 3000 and 4000 Daltons. It is to be understood that the polyoxyethylene-polyoxypropylene **block** copolymer of the present invention can be chemically bonded or cross-linked depending upon the gelling properties desired.

DETDESC:

DETD(9)

Preparation . . . present invention is described in U.S. Pat. Nos. 3,925,241 and 3,867,533, both of which are incorporated herein by reference. Illustrative **block** copolymers of the following general formula:

DETDESC:

DETD(14)

Not all of the **block** copolymers of the formula:

DETDESC:

DETD(16)

may be employed in the present invention. Because of the nature of aqueous solutions of these **block** copolymers, three variables affect the formation of the gels. These variables do not apply to the chemically branched or cross-linked. . . .

DETDESC:

DETD(17)

(1) the weight percent concentration of **block** copolymers in the gel;

DETDESC:

DETD(20)

These minimal define a minimum weight percent concentration of the **block** copolymer with a specific hydrophobe having a minimum weight percent of ethylene oxide that is necessary to form a gel.. . . minimum concentration with a specific molecular weight hydrophobe, a minimum weight percent of ethylene oxide is required before a specific **block** copolymer will form a gel in an aqueous solution. Examples of minimum weight percent concentrations with specific molecular weight hydrophobes. . . .

DETDESC:

DETD(21)

. . .
of

	Min. wt percent		
hydrophobe	concentration to	Min. weight	Total mol. wt
base	form a gel	percent ethylene	of block
		oxide required	copolymer

2250	40	50	4600
2750	40	45	4910
2750	30	60. . .	

DETDESC:

DETD(22)

At least a 40 percent weight concentration of the **block** copolymer having a hydrophobe of at least 2250 molecular weight with at least about 50 weight percent of ethylene oxide condensed therewith will be necessary to form a gel in an aqueous solution. In all cases, the **block** copolymers above the minima indicated in Table I will form gels in aqueous solutions up to 90 weight percent concentration and higher. Above 90 weight percent concentration, however, the gels tend to become indistinguishable from the starting **block** copolymer itself. It is to be understood that the molecular weight of the hydrophobe may be other than those illustrated. . . a hydrophobe of about 2500 molecular weight is used, it is recognized that a gel may be formed from the **block** copolymer at a concentration of 40 weight percent in an aqueous solution where about 45 weight percent of ethylene oxide is present in the **block** copolymer.

DETD(DESC):

DETD(35)

is . . . 4000 Daltons, the ethylene oxide content is from 70 to 90 weight percent, the total average molecular weight of the **block** polymer is from 16,000 Daltons to 20,000 Daltons and the gel composition comprises from 15 to 50 weight percent of. . .

DETD(DESC):

DETD(45)

The mechanical properties of the poloxamer gels can be altered by changing the concentration of **block** copolymer in solution, by changing the temperature of the solution, and, to a lesser extent, by varying the salt concentration. . .

DETD(DESC):

DETD(51)

The mechanism of gel formation in ethyleneoxide-propyleneoxide **block** copolymer solution in water is thought to be through the dissociation of solvent molecules from the polymer chain and the. . .

DETD(DESC):

DETD(54)

The gel is normally made by dissolving the desired concentration of salt in deionized, sterilized water and adding the polyoxyethylene/polyoxypropylene **block** copolymer to create the desired osmolarity and viscosity.

DETD(DESC):

DETD(55)

It is to be understood that several different **block** copolymers can be used in combination to manufacture the gel. In addition, conventional gelling agents can be added to the. . .

DETDESC:

DETD(62)

The elimination of **block** copolymers following parenteral or oral administration is well documented. Following intravenous injection, poloxamer 188 (Pluronic F68) rapidly distributes within the. . .

DETDESC:

DETD(66)

In . . . depending on the physical properties that are required for the particular prosthesis that is to be filled. Several different polyoxyethylene-polyoxypropylene **block** copolymers can be mixed to form the gel. Finally, the copolymers can be chemically branched or crosslinked to provide the. . .

DETDESC:

DETD(70)

To prepare 100 g of **block** copolymer gel, 20 g of poloxamer 407 are weighed into a container which can be sealed and autoclaved. 80 g. . .

DETDESC:

DETD(73)

To prepare 100 g of **block** copolymer gel with dermatan sulfate as a lubricant, 19 g of poloxamer 407 are weighed into a container which can. . .

DETDESC:

DETD(76)

To prepare 100 g of **block** copolymer gel with two copolymers, 10 g of poloxamer 407 and 12 g of poloxamer 338 are weighed into a. . .

CLAIMS:

CLMS(1)

We claim:

1. A method for providing a **prosthesis** approximating the consistency of human or animal tissue comprising the step of filling the lumen of the **prosthesis** with an aqueous solution of a polyoxyethylene-polyoxypropylene **block** copolymer having the following formula:

$$\text{HO}(\text{C.sub.2 H.sub.4 O}).\text{sub.b} (\text{C.sub.3 H.sub.6 O}).\text{sub.a} (\text{C.sub.2 H.sub.4 O}).\text{sub.b H}$$

wherein a is an. . .

CLAIMS:

CLMS(4)

4. A soft tissue **prosthesis** [with]comprising a lumen and a filler,

wherein the filler comprises an aqueous solution of a polyoxyethylene-polyoxypropylene **block** copolymer having the following formula:

$\text{HO}(\text{C.sub.2 H.sub.4 O})\text{.sub.b} (\text{C.sub.3 H.sub.6 O})\text{.sub.a} (\text{C.sub.2 H.sub.4 O})\text{.sub.b H}$

wherein a is an . . .

CLAIMS:

CLMS (5)

5. The **prosthesis** of claim 4, wherein the hydrophobe represented by $(\text{C.sub.3 H.sub.6 O})\text{.sub.a}$ has an average molecular weight of between approximately 2750. . .

CLAIMS:

CLMS (6)

6. The **prosthesis** of claim 4, wherein the hydrophobe represented by $(\text{C.sub.3 H.sub.6 O})\text{.sub.a}$ has an average molecular weight of approximately 4000 Daltons.

CLAIMS:

CLMS (7)

7. The **prosthesis** of claim 4, wherein the **prosthesis** is a breast implant.

CLAIMS:

CLMS (8)

8. A method of implanting a **prosthesis** into a human or animal comprising the steps of:
implanting the lumen of the **prosthesis** into the body of the human or animal;
filling the lumen with an aqueous solution of polyoxyethylene-polyoxypropylene **block** copolymer having the following formula:

$\text{HO}(\text{C.sub.2 H.sub.4 O})\text{.sub.b} (\text{C.sub.3 H.sub.6 O})\text{.sub.a} (\text{C.sub.2 H.sub.4 O})\text{.sub.b H}$

wherein a is an integer. . . $(\text{C.sub.2 H.sub.4 O})\text{.sub.b}$ constitutes from about 50 to 90 percent by weight of the copolymer; and, allowing the solution to **gel**.

CLAIMS:

CLMS (11)

11. The method of claim 8, wherein the **prosthesis** is a breast implant.

CLAIMS:

CLMS (12)

12. The method of claim 8, wherein the **gel** further contains an

effective amount of dermatan sulfate.

CLAIMS:

CLMS(13)

13. The method of claim 1, further comprising the step of adding a biologically compatible salt to the polyoxyethylene-polyoxypropylene **block** copolymer solution.

CLAIMS:

CLMS(15)

15. The soft tissue **prosthesis** of claim 4, wherein the filler further comprises a salt.

CLAIMS:

CLMS(16)

16. The soft tissue **prosthesis** of claim 4 wherein the filler is radiolucent.

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(FILE 'USPAT' ENTERED AT 15:52:11 ON 08 JUL 1999)

L1 7861 S PROSTHESIS
L2 1939 S L1/TI
L3 3317 S L1/CLM
L4 1690 S L2 AND L3
L5 6 S L4 AND LINER/CLM AND (KNEE OR LIMB)/CLM
L6 136 S GEL AND L4
L7 53 S L4 AND (GEL/CLM OR GEL/TI)
L8 2 S L7 AND STYRENE
L9 2 S L7 AND BLOCK

=> s 15 and gel

168863 GEL
L10 0 L5 AND GEL

=> s 15 and block

627389 BLOCK
L11 4 L5 AND BLOCK

=> s 111 and polymer

238839 POLYMER
L12 2 L11 AND POLYMER

=> d 1-2

1. 5,888,216, Mar. 30, 1999, **Prosthesis** liner for below-knee amputees; Louis J. Haberman, 623/36 [IMAGE AVAILABLE]

2. 5,258,037, Nov. 2, 1993, Prosthetic liner and method of making the

liner with a **prosthesis** socket; Carl A. Caspers, 623/36, 33 [IMAGE AVAILABLE]

=> d kwic 1-2

US PAT NO: 5,888,216 [IMAGE AVAILABLE] L12: 1 of 2
TITLE: **Prosthesis** liner for below-knee amputees

ABSTRACT:

A prosthesis liner for below-knee amputees comprising a **polymer** liner, such as silicone, incorporating a pre-flexed shape having an angle at the knee selected from 20 to 60 degrees, . . .

SUMMARY:

BSUM(12)

An object of the invention is to provide a prosthesis device with a **polymer** liner incorporating a pre-flexed angle at the knee.

SUMMARY:

BSUM(34)

The . . . results in the formation of three dimension chemical structures to which anti-bacterial agents may join. The chemical composition of the **polymer** may be altered to effect precise control of the release of the anti-bacterial agents. As prosthetic silicone liners typically have. . .

DETDESC:

DETD(3)

Referring . . . prosthesis liner according to the present invention is generally indicated by the numeral 50 and is preferably made of silicone **polymer** formed over the metal core 10 (illustrated in FIG. 1) by placing and securing the metal core 10 into a. . .

DETDESC:

DETD(8)

The . . . model blueprint and mathematical relationships are transferred to a CNC machine. The core model is then cut from a large **block** of solid aluminum. A locking key 28 (see FIG. 1) is produced as part of the upper third of the. . .

DETDESC:

DETD(11)

The . . . machining to create a 1.5 to 2 mm gap between the core model and the inner aspect of the aluminum **block**. There are instances when below-knee amputees would desire and request a prosthetic silicone liner with the features of the current. . .

DETDESC:

DETD(12)

This . . . material and cured to form the silicone liner according to the present invention. The inner, negative cavity of the aluminum **block** is polished and plated. Holes are drilled, strategically, in order to achieve proper silicone filling of the overall mold when. . .

DETDESC:

DETD(15)

Another . . . placed over the residuum, the anti-bacterial agent in the liner material is slowly released by the chemical composition of the **polymer** which may be altered to effect precise control of the release of the anti-bacterial agents. As prosthetic silicone liners typically. . .

CLAIMS:

CLMS(1)

What is claimed is:

1. A below **knee** amputee **prosthesis liner**, comprising:
a molded **polymer**-like **liner** for fitting over a below **knee** amputation **limb** of a person;
said **liner** having a lower portion with a closed distal end, a **knee** portion and an upper portion having an opening adapted for insertion of a residuum of the amputee;
said lower portion being tapered wherein the distal end of said lower portion is narrower than the lower portion proximate to said **knee** portion;
said **liner** comprising a material having a time released anti-bacterial agent in the material;
said **knee** portion having a pre-flexed angle;
an umbrella shaped flexible shuttle housing integral with the closed distal end of said lower portion of said **liner**; and
said shuttle housing having a coupling adapted for attachment to a rod which is part of a **prosthesis**.

CLAIMS:

CLMS(2)

2. The **prosthesis liner** of claim 1, further comprising a thickened band in a wall of said upper portion of said **liner** and biased toward the opening thereof.

CLAIMS:

CLMS(3)

3. The **prosthesis liner** of claim 1, further comprising at least two thickened bands in a wall of said upper portion of said **liner** and biased toward the opening thereof.

CLAIMS:

CLMS(4)

4. The **prosthesis** device of claim 3, wherein said at least two thickened bands are spaced 3/4 inch apart.

CLAIMS:

CLMS(5)

5. The **prosthesis liner** of claim 3, wherein one of said at least two thickened bands may be trimmed off to shorten said upper portion of said **liner**.

CLAIMS:

CLMS(6)

6. The **prosthesis liner** of claim 1, wherein said time released anti-bacterial agent is selected from the group consisting of "NEOSPORIN," "BACITRACIN" or "SILVEDENE."

CLAIMS:

CLMS(7)

7. The **prosthesis liner** of claim 1, wherein said pre-flexed elected from twenty to sixty degrees.

CLAIMS:

CLMS(8)

8. The **prosthesis liner** of claim 1, wherein said taper is selected from five to twelve degrees.

CLAIMS:

CLMS(9)

9. The **prosthesis liner** of claim 1, wherein said **liner** is made of flexible and clear heat-cured two part silicone.

CLAIMS:

CLMS(10)

10. The **prosthesis liner** of claim 1, wherein said coupling is threaded.

CLAIMS:

CLMS(11)

11. The **prosthesis liner** of claim 1, wherein said shuttle housing is generally circular in shape with a series of oval openings evenly spaced. . .

CLAIMS:

CLMS(12)

12. The **prosthesis liner** of claim 1, wherein said flexible

1. 5,888,216, Mar. 30, 1999, **Prosthesis** liner for below-knee amputees; Louis J. Haberman, 623/36 [IMAGE AVAILABLE]
2. 5,702,463, Dec. 30, 1997, Tibial **prosthesis** with polymeric liner and liner insertion/removal instrument; Albert Pothier, et al., 623/20; 606/99; 623/18 [IMAGE AVAILABLE]
3. 5,314,497, May 24, 1994, Apparatus and method for sealing a liner to a **prosthesis**; John N. Fay, et al., 623/34, 33, 37 [IMAGE AVAILABLE]
4. 5,258,037, Nov. 2, 1993, Prosthetic liner and method of making the liner with a **prosthesis** socket; Carl A. Caspers, 623/36, 33 [IMAGE AVAILABLE]
5. 5,171,282, Dec. 15, 1992, Femoral member for knee **prosthesis**; Michel Pequignot, 623/20, 18 [IMAGE AVAILABLE]
6. 4,094,017, Jun. 13, 1978, Knee joint **prosthesis** with patellar-femoral contact; Larry Stanford Matthews, et al., 623/20 [IMAGE AVAILABLE]

5,884,639, Mar. 23, 1999, Crystal gels with improved properties; John
Y. Chen, 132/321; 428/521; 524/270, 474, 476, 490, 505; 525/95, 98 [IMAGE
AVAILABLE]

636/36
33

✓ 1. 5,407,445, Apr. 18, 1995, ~~Gal~~ composition for implant
prosthesis and method of use; Daiva K. Tautvydas, et al., 623/8, 11,
66 [IMAGE AVAILABLE]

=> 19 1 rel art xa xp ipc

US PAT NO: 5,407,445 [IMAGE AVAILABLE]

L9: 1 of 2

REL-US-DATA: Continuation-in-part of Ser. No. 886,264, May 20, 1992,
abandoned.

ART-UNIT: 338

PRIM-EXMR: David Isabella

INT-CL: [6] A61F 2/12

US PAT NO: 5,884,639 [IMAGE AVAILABLE] L16: 1 of 5
REL-US-DATA: Continuation-in-part of Ser. No. 719,817, Sep. 30, 1996,
and a continuation-in-part of Ser. No. 665,343, Jun. 17,
1996, and a continuation-in-part of Ser. No. 612,586,
Mar. 8, 1996.

US PAT NO: 5,830,237 [IMAGE AVAILABLE] L16: 2 of 5

US PAT NO: 5,633,010 [IMAGE AVAILABLE] L16: 3 of 5
REL-US-DATA: Division of Ser. No. 351,890, Dec. 8, 1994, which is a
continuation of Ser. No. 956,616, Oct. 5, 1992,
abandoned.

US PAT NO: 5,630,844 [IMAGE AVAILABLE] L16: 4 of 5

US PAT NO: 5,622,711 [IMAGE AVAILABLE] L16: 5 of 5
REL-US-DATA: Continuation of Ser. No. 956,616, Oct. 5, 1992, abandoned.

1. 5,884,639, Mar. 23, 1999, Crystal gels with improved properties; John Y. Chen, 132/321; 428/521; 524/270, 474, 476, 490, 505; 525/95, 98 [IMAGE AVAILABLE]

2. 5,830,237, Nov. 3, 1998, **Gel** and cushioning devices; Bruce G. Kania, 623/37; 2/22; 602/62; 623/36 [IMAGE AVAILABLE]

3. 5,633,010, May 27, 1997, Adhesive compositions, wound dressings and methods; Yen-Lane Chen, 424/448, 443, 445, 447, 449; 524/528 [IMAGE AVAILABLE]

4. 5,630,844, May 20, 1997, Biocompatible hydrophobic laminate with thermoplastic elastomer layer; Aydin Dogan, et al., 623/8; 427/2.24; 623/11 [IMAGE AVAILABLE]

5. 5,622,711, Apr. 22, 1997, Adhesive composition for use as a wound dressing or ostomy/**prosthesis** adhesive; Yen-Lane Chen, 424/445, 447, 448, 449; 523/111 [IMAGE AVAILABLE]